

Appl. No. 10/601,105

Remarks*I. Support For The Amendment And Status Of The Claims*

The Title has been amended to reflect the claimed subject matter. Support for the amendment of the Title is found in application no. 10/601,105 ("the present application") at page 22, line 11 *et seq.* Support for the amendment of the Title is found in priority application no. 60/101,318 ("the '318 application") at page 24, line 4 *et seq.*

Claims 21 and 23-27 have been amended, claims 22 and 28-40 have been canceled, and new claims 41-44 have been added. Claims 21, 23-27 and 41-44 are pending.

Claims 28-40 have been canceled without prejudice to or disclaimer of the subject matter therein, in order to focus prosecution on the subject matter of claims 21, 23-27 and 41-44. Applicants reserve the right to file one or more continuation applications directed to the subject matter of canceled claims 28-40.

Support for the amendment of claim 21 is found in the present application at page 22, line 11 *et seq.*; page 22, line 30; and page 38, line 6. Support for the amendment of claim 21 is found in the '318 application at page 5, line 29; page 22, lines 8-9; page 24, line 4 *et seq.*; page 24, line 28; page 26, lines 31-32; and page 40, lines 35-36.

Support for the amendment of claim 23 is found in the present application at page 22, line 21; page 25, line 16; and page 54, line 17. Support for the amendment of claim 23 is found in the '318 application at page 24, line 17; page 24 line 23; page 27, line 19, and page 58, line 32.

Support for the amendment of claim 24 is found in the present application at page 7, line 24. Support for the amendment of claim 24 is found in the '318 application at page 5, line 31.

Support for the amendment of claim 25 is found in the present application at page 26, line 1. Support for the amendment of claim 25 is found in the '318 application at page 28, line 1.

Support for the amendment of claim 26 is found in the present application at page 7, line 27; page 25, line 15; and page 54, line 17. Support for the amendment of claim 26 is found in the '318 application at page 5, line 36; page 24, line 33; and page 58, line 32.

Support for the amendment of claim 27 is found in the present application at page 24, line 20. Support for the amendment of claim 27 is found in the '318 application at page 26, line 20.

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Support for claim 41 is found in the present application at page 26, line 1. Support for claim 41 is found in the '318 application at page 28, line 1.

Support for claim 42 is found in the present application at page 54, line 20. Support for claim 42 is found in the '318 application at page 58, line 36.

Support for claim 43 is found in the present application at page 8, line 3. Support for claim 43 is found in the '318 application at page 6, line 8.

Support for claim 44 is found in the present application at page 8, lines 5-6. Support for claim 44 is found in the '318 application at page 6, lines 12-13.

No new matter has been added by this amendment.

## *II. The Objection To The Title Should Be Withdrawn*

At page 2 of the Office Action, the Examiner objected to the Title. Applicants respectfully traverse this objection.

The Title has been amended to recite "IL-B50 Antibody." As discussed above, support for the Title is found in the present application and in the '318 application.

Applicants respectfully request that this objection be reconsidered and withdrawn.

## *III. Information Disclosure Statements*

Applicants thank the Examiner for confirming at page 2 of the Office Action that document AH (Maeurer *et al.*, *The Cytokine Handbook*, 3<sup>rd</sup> Ed., "Interleukin-7" (1998), Chapter 9: 229-269) has been considered.

Document AE (Friend *et al.*, "A Thymic Stromal Cell Line Supports *In Vitro* Development Of Surface IgM+ B Cells And Produces A Novel Growth Factor Affecting B and T Lineage Cells," *Experimental Hematology* 22(3) : 321-328 (1994) ("the Friend document")) was listed on the Form PTO/SB/08 filed July 18, 2003, but this document has not yet been considered. Filed herewith is an information disclosure statement, and the Friend document is listed, among other documents, on the accompanying Form PTO/SB/08. Also filed herewith is a copy of the Friend document. Applicants respectfully request that the Examiner indicate that the listed documents have been considered, by returning an Examiner-initialed copy of the Form PTO/SB/08 to the undersigned.

Document AB, EP 0 314 415 A2, was listed on the Form PTO/SB/08 filed July 18, 2003, but the Examiner did not initial this document on the Form PTO/SB/08. Applicants

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respectfully request that the Examiner indicate that EP 0 314 415 A2 has been considered, by returning an Examiner-initialed copy of the Form PTO/SB/08 to the undersigned.

***IV. The Written Description Rejection Should Be Withdrawn***

Claims 21 and 28-40 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. Applicants respectfully traverse this rejection.

Claims 28-40 have been canceled. With respect to the rejection of Claim 21, Applicants provide the following remarks.

***A. Claims 21 and 28-40 Are Described In The Present Application And In The '318 Application, To Which The Present Application Claims Priority***

Claim 21 has been amended to recite an isolated antibody or fragment thereof that specifically binds a polypeptide consisting of SEQ ID NO:2. As established above in Section I of this paper, the subject matter of claim 21 is described in the present application and in the '318 application.

***B. The Alleged Basis For The Written Description Rejection Is Improper***

Underlying the written description rejection is the allegation that, because the '318 application allegedly fails to disclose a utility for the claimed invention, the claimed invention does not have priority to the '318 application. According to the Examiner,

[b]ecause the specific, substantial and credible utility of the instant polypeptide consisting [sic] SEQ ID NO: 2 is only disclosed in the specification of continuation application 09/963,347 filed on 09/25/2001, the effective filing date for the instant invention is determined as the filing date of continuation application 09/963,347 i.e. 09/25/2001."

Office Action at page 3.

Applicants respectfully disagree. Utility for the claimed invention is disclosed in the '318 application. A *prima facie case* of lack of utility has not been established. As a result, the claimed invention has priority to the '318 application.

***1. Utility For The Claimed Invention Is Disclosed In The '318 Application***

***a. The Disclosed Utility Is Specific***

Because the threshold of utility is not high under 35 U.S.C. § 101, an invention is useful if it is merely capable of providing some identifiable benefit. *Juicy Whip, Inc. v.*

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*Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999). In other words, only a minimal utility is required. Here, the disclosure in the '318 application is sufficient to meet the minimal utility standard set forth in 35 U.S.C. § 101.

At least one specific utility has been disclosed in the '318 application for the polypeptide of SEQ ID NO: 2, i.e., IL-B50. For example, the '318 application discloses that IL-B50 is likely to have stimulatory or inhibitory effects on hematopoietic cells, including e.g., lymphoid cells, such as T-cells, B-cells, natural killer cells, macrophages, dendritic cells, and hematopoietic progenitors. See the '318 application at page 9, lines 9-13. The '318 application also discloses that IL-B50 may also be useful in the treatment of immune disorders, e.g., T cell immune deficiencies, chronic inflammation, or tissue rejection, or in cardiovascular or neurophysiological conditions. See the '318 application at page 13, lines 1-4.

The '318 application also discloses that IL-B50 and IL-7 are likely to share similar biological functions, (see page 12, lines 1-4), and that IL-7 exhibits strong effects on lymphopoietic development and differentiation (see page 59, lines 21-22). The '318 application also discloses that IL-B50 would bind to the alpha subunit of the IL-7 receptor along with another receptor subunit (see page 49, lines 25-28).

Evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility is supportive of an assertion of therapeutic utility for a new compound. M.P.E.P. § 2107.03, part II. One of ordinary skill in the art would have understood from the '318 application that the polypeptide of SEQ ID NO: 2 has similar functions as IL-7, such as stimulating lymphopoietic development and differentiation. As a result, an antibody or fragment thereof that binds to the polypeptide of SEQ ID NO:2 would also have specific utility.

*b. The Disclosed Utility Is Substantial*

According to the M.P.E.P., "[c]ourts have repeatedly found that the mere identification of a pharmacological activity of a compound is relevant to an asserted pharmacological use provides an 'immediate benefit to the public' and satisfies the utility requirement." M.P.E.P. § 2107.01, part III.

Here, the identification of the polypeptide of SEQ ID NO: 2 as having an effect on hematopoietic cells and having a role in treating immune disorders provides researchers and physicians with a new target for intervention in immune disorders and disease. As a result, the claimed antibody or fragment thereof has a "real world" use. Therefore, the utility

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disclosed in the '318 application for the polypeptide of SEQ ID NO: 2 and antibodies (and fragments thereof) that bind to the polypeptide of SEQ ID NO: 2 is substantial.

*c. The Disclosed Utility Is Credible*

An assertion of utility is credible unless the logic underlying the assertion is seriously flawed or the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. See M.P.E.P. § 2107.02, part III.B. Here, the utility asserted in the '318 application is credible, because of the sequence similarity between the polypeptide of SEQ ID NO: 2 and IL-7.

*2. A Prima Facie Case Of Lack Of Utility Has Not Been Established*

An asserted utility creates a presumption of utility. See M.P.E.P. § 2107.02, part III.A. The M.P.E.P. also cautions that "Office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to be false, based on the technical field of the invention or for other general reasons." *Id.* Rather, "any inquiry must start by asking if there is any reason to question the truth of the statement of utility." *Id.*

Indeed, the Examiner bears the initial burden of showing that a claimed invention lacks utility. *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence . . ."); M.P.E.P. § 2107.02, part IV.

Here, the Examiner has not provided *any* reasons or evidence why the '318 application allegedly fails to set forth a specific, substantial, and credible utility for the claimed invention. At best, the Examiner has merely stated that utility is disclosed in application no. 09/963,347. However, merely providing a conclusory statement that utility is found, at the earliest, in application no. 09/963,347 is insufficient to establish a *prima facie* case of lack of utility. Absent the establishment of a *prima facie* case of lack of utility, the allegation that the claimed invention is not entitled to priority in the '318 application is improper.

*B. Summary*

Utility for the claimed invention is disclosed in the present application and in the '318 application. A *prima facie* case of lack of utility has not been established.

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As a result, the alleged basis for the lack of written description is improper. Applicants respectfully request that this rejection be reconsidered and withdrawn.

**V. The Lack Of Novelty Rejection Should Be Withdrawn**

Claims 21-23, 26-28 and 31-35 stand rejected under 35 U.S.C. § 102(e) as allegedly lacking novelty over U.S. Patent No. 6,555,520 ("the '520 patent"). Applicants respectfully traverse this rejection. Claims 22, 28 and 31-35 have been canceled. With respect to Claims 21, 23, 26 and 27, Applicants provide the following remarks.

As established above in Section IV of this paper, the claimed subject matter has priority to the '318 application, which was filed on September 21, 1998. As a result, the '520 patent is not available as prior art, because the earliest application to which the '520 patent claims priority was filed on November 13, 1998, i.e., after the September 21, 1998 filing date of the '318 application.

Applicants respectfully request that this rejection be reconsidered and withdrawn.

**VI. The Obviousness Rejections Should Be Withdrawn****A. The Rejection Of Claims 24, 25, 29 and 30 Should Be Withdrawn**

Claims 24, 25, 29 and 30 stand rejected under 35 U.S.C. § 103, as allegedly obvious over the '520 patent in view of Gavilondo *et al.*, *BioTechniques* 29: 128-145 (2000). Applicants respectfully traverse this rejection. Claims 29 and 30 have been canceled. With respect to claims 24 and 25, Applicants provide the following remarks.

A *prima facie* case of obviousness has not been set forth. As established above, the '520 patent is not available as prior art against the claimed subject matter, because the claimed subject matter has priority to the '318 application, which was filed on September 21, 1998. Thus, there is no basis for this rejection. Applicants respectfully request that this rejection be reconsidered and withdrawn.

**B. The Rejection Of Claims 36-38 Should Be Withdrawn**

Claims 36-38 stand rejected under 35 U.S.C. § 103, as allegedly obvious over the '520 patent in view of U.S. patent no. 4,281,061 ("the '061 patent"). Applicants respectfully traverse this rejection.

A *prima facie* case of obviousness has not been set forth. As established above, the '520 patent is not available as prior art against the claimed subject matter, because the

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claimed subject matter has priority to the '318 application, which was filed on September 21, 1998. Thus, there is no basis for this rejection.

At any rate, Claims 36-38 have been canceled. Applicants respectfully request that this rejection be reconsidered and withdrawn.

***C. The Rejection Of Claims 39 and 40 Should Be Withdrawn***

Claims 39 and 40 stand rejected under 35 U.S.C. § 103, as allegedly obvious over the '520 patent in view of the '061 patent and U.S. patent no. 5,627,043. Applicants respectfully traverse this rejection.

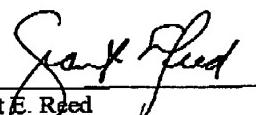
A *prima facie* case of obviousness has not been set forth. As established above, the '520 patent is not available as prior art against the claimed subject matter, because the claimed subject matter has priority to the '318 application, which was filed on September 21, 1998. Thus, there is no basis for this rejection.

At any rate, Claims 39 and 40 have been canceled. Applicants respectfully request that this rejection be reconsidered and withdrawn.

**Conclusion**

It is believed that each of the objections and rejections in the Office Action have been addressed.

Respectfully submitted,



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